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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,089	08/21/2003	David Ernest Hartley	PA-5340 -RFB	7302

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,089	HARTLEY ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,7-9,11,12,28,35,42 and 44-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,7-9,11,12,28,35,42 and 44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2009 has been entered.

2. This Office action is responsive to an amendment filed May 28, 2009. Claims 3-4, 7-9, 11-12, 28, 35, 42 & 44-49 are pending. Claims 3-4, 7-9, 11-12, 28, 35, 42 & 44-47 have been amended. Claims 1-2, 5-6, 10, 13, 15-27 and 29-34 have been cancelled. New claims 48-49 have been added.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numeral "53" is disclosed in figure 8; however, there is no corresponding reference numeral in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each

drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 7-8 & 11-12 are objected to because of the following informalities:

In regards to claims 7-8, at lines 1-2, the limitations "the proximal wire coil" lack sufficient antecedent basis; for example, there is no previous recitation of a proximal wire coil prior to this recitation in the claims. Moreover, the claims appear to depend from claim 4, which recites "a proximal wire coil" at line 2.

In regards to claims 11-12, at line 1, the limitations "the distal wire coil" lack sufficient antecedent basis; for example, there is no previous recitation of a distal wire coil prior to this recitation in the claims. Moreover, the claims appear to depend from claim 9, which recites "a distal wire coil" at line 3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3-4, 7-9, 11-12, 28, 35, 42 & 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's newly submitted claims 48-49 require a "semi-stiff zone [of the distal zone to have] a proximal portion of high stiffness adjacent to the distal portion of the central zone"; however, judging from figs. 8-9 of the Applicant's original disclosure and their respective descriptions, the Examiner finds no support for a semi-stiff zone having a high stiffness portion; for example, the Applicant's semi-stiff zone 60 cannot have the same stiffness along the length thereof as the central elongate portion 50 (i.e. both are made of the same material). The rest of the disclosure does not support such an interpretation either. A similar argument applies to the other claimed portions or zones, wherein the Applicant now claims a distinct zone to simultaneously include two different stiffnesses when in fact, reading from the specification, it is clear that the zones are distinguished from each other by the mere fact that they each have a distinct particular stiffness as opposed to overlapping stiffnesses such that the guidewire as a whole has a smooth stiffness transition resulting from an incremental change in stiffness with each zone (i.e. each zone has its own distinct stiffness different from that of any adjacent zone). As such, the Examiner submits that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 3-4, 8-9, 12, 44, 46 & 48-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (US 5,421, 349) in view of Stevens et al. (US 5,584,803), and further in view of Chaisson et al. (US 6,086,548).

In regards to **claims 48-49**, **Rodriguez et al.** disclose a guide wire 10, the guide wire 10 having 5 zones of varying stiffness (see drawing below) comprising:

(a) a proximal end and a distal end;

(b) a fifth proximal zone adjacent the proximal end and having a semi-stiff proximal portion, a distal portion of high-stiffness, and a transition portion transitioning from the semi-stiffness of the proximal portion to the high stiffness of the distal portion, the proximal zone having a length of about 5 cm (i.e. "the proximal end tip preferably has a length of no more than about two inches") (see col. 2, lines 27-31);

(c) a fourth elongate central zone of high stiffness adjacent the proximal zone having a substantially constant diameter along its length; and,

(d) a distal zone adjacent to the high stiffness central zone and having a proximal portion of high-stiffness adjacent to the distal portion of the central zone and transitioning to a distal portion of highest flexibility when the distal zone comprises three zones:

(i) a third semi stiff zone having a proximal portion of high stiffness adjacent to the distal portion of the central zone transitioning to a distal portion of semi-stiffness;

(ii) a second transition zone having a semi-stiff proximal portion adjacent to the distal portion of the semi-stiff zone transitioning to a flexible distal portion; and,

(iii) a first flexible zone adjacent to the distal end and having a flexible proximal portion adjacent to the distal portion of the transition zone transitioning to a distal portion of at least stiffness and highest flexibility;

wherein the proximal zone comprises a proximal wire coil 30 of substantially constant diameter and the distal zone comprises a distal wire coil 18 of substantially constant diameter (see figs. 1-2; col. 2, lines 19-20, 27-31, 42-44 & 66-68; col. 3, lines 26-29 & 41-44; see claims 1 & 4 of Rodriguez);

wherein the first distal zone includes a distal tip pre-formed curve having a single direction of curvature having the highest flexibility (see fig. 1; col. 3, lines 7-8).

In regards to **claim 4**, Rodriguez et al. disclose a guide wire 10 wherein the proximal zone comprises a tapered mandrel with a proximal wire coil 30 of substantially constant coil diameter on and extending along the tapered mandrel (see fig. 2).

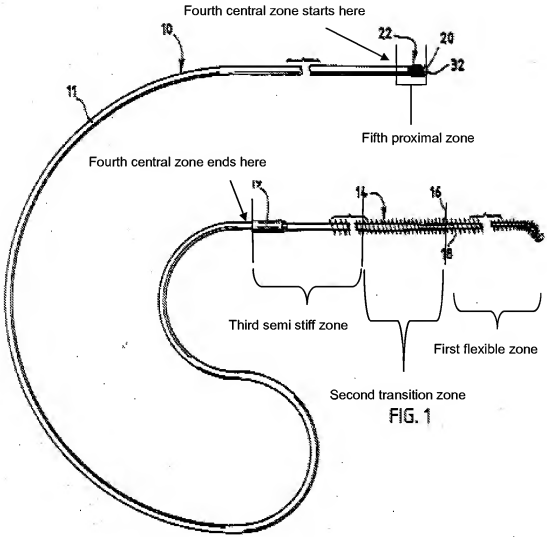

FIG. 1

proximal wire coil 30 terminates in a rounded tip 32 (see fig. 2; col. 3, lines 36-41).

In regards to **claim 9**, Rodriguez et al. disclose a guide wire 10 wherein the distal zone comprises in order from the fourth elongate central zone: a tapered mandrel portion and a portion 16 of constant reduced diameter with a distal wire coil 18 of

substantially constant coil diameter on and extending along the tapered mandrel portion and the portion 16 of constant reduced diameter (see fig. 1).

In regards to **claims 12 & 46**, Rodriguez et al. disclose a guide wire 10 wherein the distal wire coil 18 of the first flexible zone terminates in a rounded tip (see fig. 1).

In regards to **claim 44**, Rodriguez et al. disclose a guide wire 10 having a transition from full stiffness to semi-stiff at the proximal end, the semi-stiff proximal portion providing flexibility to allow the interventional delivery system to be loaded onto the wire 10 and advanced without becoming jammed in the interior of the device (see figs. 1-2).

Rodriguez et al. teach a guide wire, as described above, that fails to explicitly teach a distal zone having a distal pre-formed curve with a radius of curvature of from 5 cm to 15 cm or J-tip zone with a radius of curvature of from 5 to 20 mm.

However, **Stevens et al.** teach that it is known to provide endovascular guidewire 440 with a first distal pre-formed U-shaped curve 446 for insertion into a thoracic arch region of an aorta such that the distal curve defines a radius of curvature of about 5 cm to 8 cm so as to generally conform in shape to the aortic arch (see fig. 36a; see col. 8, lines 34-37 & 52-67; col. 9, lines 1-10, 15-20, 35-38 & 48-52; col. 41, lines 66-67; col. 42, lines 1-10); wherein the guidewire 440 comprises a stainless steel mandrel (see col. 42, lines 5-8).

Furthermore, **Chaisson et al.** teach that it is known to provide endovascular devices for insertion into a thoracic arch region of an aorta with a J-shaped distal tip

having a radius of curvature of about 20 mm (see abstract; see figs. 5 & 9; col. 4, lines 35-37).

In regards to **claims 4, 8-9, 12, 44, 46 & 48-49**, both Rodriguez et al. and Stevens et al. teach guidewires; since Stevens et al. teach a guidewire having first preformed curve 446 having a radius of curvature corresponding to the curvature of the patient's aortic arch (i.e. in a range of 5 cm to 8 cm) so as to shape the distal portion of an endovascular catheter 320 such that it generally conforms to at least a portion of the patient's aortic arch (see fig. 36a; col. 41, lines 66-67; col. 42, lines 1-12), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Rodriguez et al. with a first preformed curve having a radius of curvature corresponding to the curvature of the patient's aortic arch (i.e. in a range of 20 to 80 mm) as taught by Stevens et al. in order to shape the distal portion of an endovascular catheter such that it generally conforms to at least a portion of the patient's aortic arch.

Moreover, since Rodriguez et al. teach that the distal end 14 may be curved (see fig. 1; see col. 3, lines 7-8) and Chaisson et al. teach that it is known to provide endovascular devices for insertion into a thoracic arch region of an aorta with a distal tip curve having a radius of curvature of about 20 mm (see abstract; see figs. 5 & 9; col. 4, lines 35-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Stevens et al., above, with a tip zone having a single direction of curvature having a radius of curvature of 20 mm as taught by Chaisson et al. in order to reduce the

likelihood of trauma caused by the advancing guide wire, including reducing the likelihood of trauma caused by the guidewire contacting the aortic valve. Moreover, Moreover, the combination can contact the aortic valve without penetrating or causing damage to the valve. Similarly, it has previously been held that merely changing size (i.e. the radius of curvature of the distal end tip) is an obvious expedient--see *In re Rose, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955).*

In regards to **claim 3**, since Stevens et al. teach a guidewire having a stainless steel mandrel is biocompatible with a bending stiffness greater than that of a catheter so as to deflect the distal portion of the catheter into the desired shape (see col. 42, lines 5-8), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Stevens et al. and Chaisson et al., above, with a stainless steel central portion as taught by Stevens et al. in order to provide a mandrel that is biocompatible with a bending stiffness greater than that of a catheter so as to deflect the distal portion of the catheter into the desired shape.

9. **Claims 28, 35, 45 & 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (' 349) in view of Stevens et al. ('803), Chaisson et al. ('548), and further in view of Ferrera (US 6,165,140).

Rodriguez et al. as modified by Stevens et al. and Chaisson et al. disclose a guide wire, as described above, that fails to explicitly teach a radiopaque guide wire or a polytetrafluoroethylene coated wire coil.

However, **Ferrera** discloses a guide wire comprising a radiopaque guide wire and a wire coil having a portion 40 coated with polytetrafluoroethylene (PTFE) (see col. 3, lines 42-48).

In regards to **claims 28 & 47,** it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Stevens et al. and Chaisson et al. with a radiopaque coil as taught by Ferrera in order to increase the visibility of the guide wire under fluoroscopy.

In regards to **claims 35 & 45,** it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Stevens et al. and Chaisson et al. with a PTFE coating as taught by Ferrera in order to improve the lubricity of the guide wire and fixedly maintain the wire coil in place.

10. **Claims 7 & 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (' 349) in view of Stevens et al. ('803), Chaisson et al. ('548), and further in view of Clayman et al. (US 6,716,183).

Rodriguez et al. as modified by Stevens et al. and Chaisson et al. disclose a guide wire, as described above, that fails to explicitly teach coils that are laser welded toe the mandrel portion.

However, **Clayman et al.** disclose(s) a guide wire to assist in anatomic deployment, the guide wire having: an elongate central zone 18 of high stiffness, and

substantally constant diameter along its length; a proximal zone 21 of transition from high stiffness to semi-stiffness and having a length; and a tapered segmental distal zone 16 of transition from high stiffness to being relatively flexible; wherein the proximal zone 21 comprises a tapered mandrel with a proximal wire coil 41 of substantially constant coil diameter on and extending along the tapered mandrel; wherein the proximal wire coil is laser welded to the tapered mandrel (see fig. 7; column 6/lines 45-48); wherein the proximal wire coil terminates in a rounded tip 50 (see fig. 2).

Since Rodriguez et al. teach a wire coil that is epoxied (i.e. semi-permanent attachment) or soldered (i.e. permanent attachment) in order to attach the wire coil to the shaft (see col. 3, lines 45-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Stevens et al. and Chaisson et al. with laser welded wire coil as taught by Clayman et al. in order to permanently attach the wire coil to the shaft.

11. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. ('349) in view of Stevens et al. ('803), Chaisson et al. ('548), and further in view of Baker et al. (US 5,693,083).

Rodriguez et al. as modified by Stevens et al. and Chaisson et al. teach a guidewire, as described above, that fails to explicitly teach a J-shaped tip.

However, **Baker et al.** teach that it is known to provide an endovascular guidewire 56 with a J-shaped tip zone having a single direction of curvature (see figs. 36-41).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Rodriguez et al. as modified by Stevens et al. and Chaisson et al. with a J-shaped tip as taught by Baker et al. in order to reduce the likelihood of trauma caused by the advancing guidewire.

12. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. ('349) in view of Stevens et al. ('803), Chaisson et al. ('548), and further in view of McNamara et al. (US 6,254,550).

Rodriguez et al. as modified by Stevens et al. and Chaisson et al. teach a guidewire, as described above, that fails to explicitly teach a J-shaped tip.

However, **McNamara et al.** teach that it is known to provide endovascular guide wire 10 with a J-shaped tip zone having a single direction of curvature to reduce the likelihood of trauma caused by the advancing guidewire 10 (see fig. 1 & col. 6, lines 35-44).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Rodriguez et al. as modified by Stevens et al. and Chaisson et al. with a J-shaped tip as taught by McNamara et al. in order to reduce the likelihood of trauma caused by the advancing guidewire.

Response to Arguments

13. Applicant's arguments filed May 28, 2009 have been fully considered but they are not persuasive. Applicant argues that Rodriguez et al. fail to teach the three zones within the distal zone or the respective stiffness of each of the five zones. Applicant also

argues that none of the references teach a preformed curve or a distal preformed tip curve.

In response to the Applicant's argument that Rodriguez et al. fail to teach the three zones within the distal zone or the respective stiffness of each of the five zones, the Examine respectfully traverses. The Examiner first observes that Applicant's newly submitted claims 48-49 require a "semi-stiff zone [of the distal zone to have] a proximal portion of high stiffness adjacent to the distal portion of the central zone"; however, judging from figs. 8-9 of the Applicant's original disclosure and their respective descriptions, the Examiner finds no support for a semi-stiff zone having a high stiffness portion; for example, the Applicant's semi-stiff zone 60 cannot have the same stiffness at any point along the length thereof as the central elongate portion 50 (i.e. both are made of the same material). The rest of the disclosure does not support such an interpretation either. A similar argument applies to the other claimed portions or zones, wherein the Applicant now claims a distinct zone to simultaneously include two different stiffnesses when in fact, reading from the specifications, it is clear that the zones are distinguished from each other by the mere fact that they each have a distinct particular stiffness as opposed to overlapping stiffnesses such that the guidewire as a whole has a smooth stiffness transition resulting from an incremental change in stiffness with each zone (i.e. each zone has its own distinct stiffness different from that of any adjacent zone). As such, the Examiner submits that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner also notes that contrary to the Applicant's contention, Rodriguez et al. teach at least 5 distinct zones of varying stiffness substantially as depicted in the rejections supra. For example, both the proximal zone and the distal zone of Rodriguez et al. are of a stiffness, which is less than that of the central elongate zone based on a range of diameters that is reduced from the central elongate zone to the tips (see col. 2, lines 3-18); similarly, the distal end tip is of greater flexibility than both the proximal end and the central portion (see abstract). As such, Rodriguez et al. fully teach at least 5 zones of varying stiffness. Furthermore, when given a broad reasonable interpretation, the boundaries of the respective zones may be made arbitrary; for example, rather than defining the proximal zone as stopping at the beginning of the main portion 11 of Rodriguez et al., a proximal zone may be construed to include not only the "reduced diameter guidewire portion 28" of Rodriguez et al. but also a small proximal portion of the "main body 11" of Rodriguez et al., thereby achieving a proximal zone comprising a semi-stiff part and a stiff part. Similarly, the proximal portion of the distal zone (i.e. the "semi-stiff zone") may be redefined to further include a small distal portion of the "main body 11" so as to thereby achieve a semi-stiff zone comprising both a semi-stiff part and a high stiffness part. As such, the Examiner submits that Rodriguez et al. does teach a semi-stiff zone that may be construed to include both a semi-stiff portion and high-stiffness portion. Furthermore, Rodriguez et al. teach at col. 2, lines 27-31, that "preferably, the length of wire of the proximal end tip preferably has a length of no more

than about two inches." [Emphasis added]. Rodriguez et al. thus do teach a proximal zone having a length of no more than about 2 inches (5.08 cm). As such, whether Rodriguez et al. disclose other preferred guidewire proximal zone lengths that fall outside of the Applicant's claimed range is irrelevant since Rodriguez et al. fully teach a guidewire proximal zone having a length of no more than about 2 inches (5.08 cm). Therefore, Rodriguez et al. fully anticipate a guidewire proximal zone having a length of no more than about 2 inches or 5.08 cm, which falls within the Applicant's claimed range.

In regards to the Applicant's contention that none of the references teach a preformed curve or a distal preformed tip curve, the Examiner respectfully traverses. The Examiner notes Stevens et al. teach a guidewire 440 as better depicted in fig. 36a with a first distal pre-formed U-shaped curve 446 for insertion into a thoracic arch region of an aorta such that the pre-formed curve 446 defines a radius of curvature that allows it "to generally conform to at least a portion of the patient's aortic arch" (see col. 42, lines 1-12). Stevens et al. further states that "preferably, the U-shaped distal portion has a curvature corresponding to the curvature of the patient's aortic arch, usually having a radius of curvature in a range of 20 to 80 mm" (see col. 8, lines 61-67). in shape to the aortic arch. As such, Stevens et al. fully anticipates a guidewire having a preformed curve having a radius between 20 to 80 mm, including 50 to 80 mm (i.e. 5cm to 8 cm). Furthermore, Rodriguez et al. teach a guidewire that "may have a curve near the distal end 14" (see col. 3, lines 7-8); wherein the curve has a single direction of curvature (see figure 1). As such, contrary to the Applicant's contention that the Examiner's rejection is

based on a tip curve teaching as taught in Chaisson et al., the Examiner observes that the teaching of Chaisson was merely used to illustrate the claimed tip curve radius of 20 mm (see abstract) as opposed to a whole teaching of tip curve having a single direction of curvature. Nonetheless, Chaisson et al. teach that the addition of a second direction of curvature at the distal end 31 (see fig. 5) helps the endovascular device 30 enter the right subclavian artery (see figs. 9-10). As such, removing the second direction of curvature at the distal end 31 (see fig. 5) appears to be an obvious expedient. For example, it has previously been held that merely removing an element (i.e. the second direction of curvature) and its function (i.e. to help the endovascular device enter the right subclavian artery) is not patentable--See In *re Karlson, 311 F.2d 581, 583, 136 USPQ 184, 186 (CCPA 1963); In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).* Furthermore, several cited prior arts explicitly disclose preformed J-shaped guidewire tip curves, which are ubiquitously known to exist in the art and to reduce the likelihood of trauma caused by the advancing guidewire (see instant rejections of claim 42 above).

In view of the foregoing, the rejections over at least one of Rodriguez et al., Stevens and Chaisson are maintained.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736